

<b>Case Number:</b>	CM14-0041033		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	08/08/2011
<b>Decision Date:</b>	08/19/2014	<b>UR Denial Date:</b>	03/12/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/08/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Texas and Oklahoma. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 43-year-old male who reported an injury on 08/08/2011. The injured worker was noted to be utilizing topical creams as of 08/2013. The mechanism of injury was the injured worker lacerated his right knee while using a skill saw and he fell. Prior treatments included physical therapy and medications as well as right knee surgery on 08/09/2011. The most recent documentation submitted for review was dated 01/22/2014. The injured worker had +3 tenderness to palpation at the L3 to L5 spinous processes and lumbar paravertebral muscles. There were muscle spasms of the lumbar paravertebral muscles. The diagnoses included lumbar musculoligamentous injury, lumbar radiculopathy, and right hip internal derangement, right hip sprain/strain, and right knee internal derangement as well as loss of sleep. The treatment plan included continuation of medications including topicals.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Capsasin 0.025%, Flurbiprofen 15%, Menthol 2%, Camphor 2% (240 grams): Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Federal Drug Administration (FDA).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Topical Capsaicin, Topical Salicylates Page(s): 72, 111, 28, 105.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The California MTUS guidelines recommend Topical Salicylates. The clinical documentation submitted for review failed to provide documentation of objective functional benefit that was received as well as an objective decrease in pain. There was a lack of documentation indicating a necessity for two topicals with flurbiprofen. The clinical documentation indicated the injured worker had been utilizing topicals since at least 08/2013. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Capsaicin 0.025%, Flurbiprofen 15%, Menthol 2%, Camphor 2% (240 grams) is not medically necessary.

**Flurbiprofen 25%, Cyclobenzaprine 02% (240 GRAMS): Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Federal Drug Administration (FDA).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical Analgesics, Topical Cyclobenzaprine Page(s): 72, 111, 113.

**Decision rationale:** California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. The clinical documentation submitted for

review failed to provide documented rationale for the necessity for two topicals with flurbiprofen. There was a lack of documentation of efficacy for the requested medication. The clinical documentation indicated the injured worker had been utilizing the medication since at least 08/2013. Given the above, the request for Flurbiprofen 25%, Cyclobenzaprine 02% (240 grams) is not medically necessary.

**Gabapentin 10%, Lid.:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Federal Drug Administration (FDA).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Topical Gabapentin Page(s): 113.

**Decision rationale:** The California MTUS indicate that, "topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended...Topical Salicylates are recommended...Gabapentin is not recommended" There is no peer-reviewed literature to support use. The clinical documentation submitted for review indicated the injured worker had been using topical medications since at least 08/2013. There was a lack of documented efficacy for the requested medication. Additionally, the request as submitted failed to indicate the frequency and the quantity for the requested medication as well as the other components. There was a lack of documentation of the quantity of medication being requested. Given the above, and the lack of documentation of exceptional factors to warrant non-adherence to Guideline recommendations, the request for Gabapentin 10%, Lid (Lidocaine) is not medically necessary.